

REMARKS

Applicants thank the Examiner for the consideration given the present application. Upon entry of the claim amendments herein, Claims 17-20, 22, 25-27 will be pending in the present application. Applicants have amended Claims 17, 22 and 25 and canceled Claims 21, 23-24 and 28. No new Claims have been added and no new matter is presented.

Specifically, Claim 17 has been amended to change the phrase "two or more vitamins" to "two or more fat-soluble vitamins." Support for this amendment is found in the Specification at page 6, lines 12-15. Additionally, Claim 17 has been amended to add the language "wherein the beverage composition is ready-to-drink and comprises at least about 50% water." Support for this amendment is found in Claim 23 as originally filed.

Claims 22 and 25 have been amended to modify their dependency.

Claim Objection

The Examiner has objected to Claim 24 as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants have herein cancelled Claim 24, thus, the objection thereto will not be discussed further.

Synopsis of the Invention

The present invention is directed to beverage compositions containing supplemental vitamins. Vitamin supplementation is common in the field of beverage compositions. However, vitamin solubility can be a serious problem when formulating beverage compositions with fat-soluble vitamins, such as vitamins A, D and E, which cause such formulation to be either unfeasible or unacceptable due to insolubility and, ultimately, instability of the desired vitamin supplement. In such compositions, the vitamin may ultimately settle to the bottom of a container which holds the composition.

It is therefore important to develop methods in which fat-soluble vitamins may be solubilized or stabilized in ready-to-drink beverage composition. Various methods have been attempted and are commonly used, for example, emulsification. However, emulsifiers typically utilized do not provide any nutritive benefit in addition to support of the vitamin in the beverage composition.

The present inventors have quite surprisingly discovered that foregoing problems are overcome in ready-to-drink beverage compositions comprising a fiber known as arabinogalactan and fat-soluble vitamins, including vitamin A, vitamin D and vitamin E. The arabinogalactan fiber is useful for providing a dietary fiber benefit to the consumer, as well as additional benefits in the field of immune function. It is therefore quite exciting that this fiber may be used, not only

to provide these benefits, but also to stabilize the defined vitamins as well. In addition, use of a fiber to attempt this purpose would ordinarily result in increased viscosity and likely unacceptability of the final beverage product. However, it has further been found that the arabinogalactan fiber is not precluded from use due to any problems associated with viscosity. In fact, the beverage compositions of the present invention provide excellent viscosity, which is acceptable to the consumer.

The Rejection under 35 U.S.C. § 102

The Examiner has rejected Claims 17 and 18 under 35 U.S.C. § 102 (b) as being anticipated by McAnalley, WO 98/06418 (herein “McAnalley”). Additionally, the Examiner has rejected Claim 17 under 35 U.S.C. § 102 (b) as being anticipated by Chen et al., EP 1106174 A1 (herein “Chen”). Each rejection is addressed below.

Examiner’s Rejection

The Examiner has used McAnalley to reject Claims 17-18 as being anticipated under 35 U.S.C. § 102(b). In particular, the Examiner argues that McAnalley discloses a composition as in Claim 17, which can be in liquid form, and is therefore considered a beverage. Moreover, the Examiner states that the McAnalley composition contains arabinogalactan and vitamins A, D, and E and is within the ranges claimed in Claim 18.

Similarly, the Examiner argues that Chen discloses a beverage composition containing arabinogalactan and vitamins A, D and E as in the present Claim 17.

Applicants’ Argument

Under 35 U.S.C. § 102, a claim is anticipated only if each and every claim element is found, either expressly or inherently disclosed, in a single prior art reference. See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. See *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997). Additionally, there must be no difference between what is claimed and what is disclosed in the applied reference. See *Scripps v. Genetech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Moreover, it is incumbent on the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990).

As aforementioned, the Examiner has rejected Claims 17 and 18 under 35 U.S.C. as being anticipated by McAnalley. While Applicants respectfully disagree with the Examiner's conclusion of anticipation, in a sincere effort to advance prosecution, Applicants have herein amended Claim 17 to require "two or more *fat-soluble* vitamins selected from the group consisting of vitamin A, vitamin D and vitamin E." Additionally, Applicants have added the language "*wherein the beverage composition is ready-to-drink and comprises at least about 50% water.*" Applicants respectfully assert that McAnalley fails to teach the particular combination of arabinogalactan with two or more fat-soluble vitamins in a ready-to-drink beverage composition, and therefore, fails to teach *each and every* claim element of the present invention. Rather, McAnalley broadly discloses dietary supplements containing saccharides and, in one variation, vitamins and minerals, and in another variation liquids. As amended herein, the present invention specifically requires the combination of arabinogalactan and two or more fat-soluble vitamins in a ready-to-drink beverage having at least about 50% water, in order to achieve the previously discussed surprising benefits of improved solubility and stability. Because McAnalley fails to teach this specific combination, as required to do under 35 U.S.C. § 102, Applicants respectfully assert that McAnalley fails to anticipate the present invention as amended herein.

Moreover, Applicants respectfully assert that McAnalley fails to meet the requirement that there be no difference between what is claimed and what is disclosed in the applied reference. As aforementioned, the present inventors have surprisingly discovered that the combination of arabinogalactan and two or more fat-soluble vitamins provides increased solubility and stability to the ready-to-drink beverage compositions disclosed herein. In contrast, the dietary supplements of McAnalley are generally taught as capsules, tablets or powders. See Examples 1 and 2. Moreover, the "liquid" disclosed on page 14, lines 16-24, cannot be said to be analogous to the present beverage compositions as argued by the Examiner. The American Heritage Dictionary, College Ed., 1991, defines 'liquid' as "the state of matter in which a substance exhibits a characteristic readiness to flow, little or no tendency to disperse, and relatively high incompressibility." Meanwhile, 'beverage' is defined as "any of various liquids for drinking." Thus, while a 'beverage' is a 'liquid,' a 'liquid' is *not necessarily* a 'beverage.' Therefore, it is improper to presume the 'liquid' disclosed in McAnalley is commensurate in scope with the beverage compositions of the present invention. For example, the liquid disclosed in McAnalley could be intended for topical application only. It is unclear from the disclosure of McAnalley what a liquid is, however, it is clear that no where does McAnalley teach the 'beverages' of the present invention. Thus, because 'liquid' is not tantamount to 'beverage,' Applicants respectfully assert that McAnalley fails to meet the requirement that there be no difference between what is claimed and what is disclosed in the applied reference.

Additionally, Applicants respectfully assert that McAnalley requires the inclusion of water-soluble vitamins and minerals. See *McAnalley*, Claim 17. Applicants respectfully assert that this requirement of water-soluble vitamins and minerals presents a substantial difference from the present invention. Because McAnalley teaches a substantially different formulation than disclosed herein, Applicants respectfully assert that for this additional reason, McAnalley fails to satisfy the requirement that there is no difference between what is claimed and what is disclosed in the applied reference.

Thus, because McAnalley fails to teach each and every element of the invention disclosed herein, and because there are differences between the present claims and the disclosure of McAnalley, Applicants respectfully assert that McAnalley fails to anticipate the present invention under 35 U.S.C. § 102, and respectfully request the rejection be withdrawn.

Similarly, Applicants respectfully assert that Chen fails to teach each and every element of the present invention. Namely, Chen fails to teach a beverage composition which requires the inclusion of two or more fat-soluble vitamins. Additionally, Chen fails to teach a beverage composition that, as amended herein, is ready-to-drink and comprises at least about 50% water. The ‘beverages’ mentioned in the Abstract of Chen are actually reconstituted from a powder matrix immediately prior to consumption, the matrix comprising a gum and at least one vitamin. See Chen page 6, lines 2-3. Additionally, Applicants respectfully assert that the Examiner’s argument that the matrix of Chen may be added directly to water to form a beverage is incorrect. In fact, Chen states that “the beverages of this invention are preferably obtained by adding to a beverage a powder composition of this invention.” See Chen page 6, lines 2-3. Thus, contrary to the Examiner’s statement, the composition of Chen *must* first be made into a powder before reconstitution with a beverage. This is contrary to the teachings of the present invention which provide for a ready-to-drink beverage that is stable rather than reconstituted immediately prior to use. For these reasons, Applicants respectfully assert that Chen fails to teach each and every element of the present invention.

Therefore, for all of these reasons, Applicants respectfully assert that the cited references fail to anticipate the present invention and thus, withdrawal of the present rejections under 35 U.S.C. § 102 (b) is respectfully requested.

The Rejection under 35 U.S.C. § 103

The Examiner has rejected Claims 19-28 under 35 U.S.C. § 103 as being obvious in view of McAnalley in view of Chen. As Claims 21 and 28 have been cancelled herein, and their contents have not been added to a presently pending claim, the rejections relating to these claims will not be discussed. Additionally, though the following arguments relate to Claims 19-28,

Applicants respectfully assert that the same arguments are equally applicable to Claims 17 and 18. For the following reasons, Applicants respectfully traverse this rejection.

The Rejection and Cited Art

The Examiner has rejected Claims 19-28 under 35 U.S.C. §103 as obvious over McAnalley in view of Chen. McAnalley generally discloses the use of plant carbohydrates for dietary supplements and nutritional support for promotion and maintenance of good health. Such supplements may include phytonutrients, vitamins, minerals, herbal extracts and other non-toxic nutrients. Additionally, these supplements are preferably administered orally, in the form of a capsule or tablet, or topically, in the form of a lotion or cream.

Chen generally discloses powder compositions having a matrix comprised of a gum and at least one fat-soluble vitamin. The powder may be incorporated into products such as foods, cosmetics and reconstituted beverages.

Specifically, the Examiner states that Chen teaches the use of gums at about 5% in an aqueous solution, and in particular, in a matrix comprising the gum or gums and at least one vitamin. The Examiner continues by stating that the matrix can either be added to water to make a beverage or mixed with other dry ingredients to make a powder. Thus, the Examiner concludes that since Chen teaches it is acceptable to use about 5% of a gum, and arabinogalactan can be a gum, it would be obvious to use about 5% of a gum in the compositions of McAnalley.

Next, the Examiner relies on Chen and McAnalley to teach the use of arabinogalactan from the larch tree, as well as “nutritionally effective” amounts of vitamins, which arguably fall within the ranged claimed presently. Additionally, the Examiner relies on Chen to teach a beverage with various amounts of the composition powder used in conjunction with more than 50% water, and McAnalley to teach a ‘liquid.’ The Examiner points out that no distinction is seen between the ‘beverages’ of Chen and the ‘liquids’ of McAnalley, and thus, it would be obvious to use the particular amount of water disclosed in Chen to make the ‘liquid’ disclosed in McAnalley, which also contain arabinogalactan and vitamins.

Additionally, the Examiner admits that both Chen and McAnalley fail to teach the particular pH value claimed herein, and in fact, fail to even disclose a pH value for the compositions taught therein. However, the Examiner concludes that it would have been obvious to make the beverage of McAnalley which has the presently disclosed pH range because the examples in Chen disclose compositions which would have this particular pH range. Finally, the Examiner states that McAnalley discloses the use of beta-carotene, and Chen discloses the use of E acetate, as claimed in the present Claim 27.

The Argument

The Examiner bears the burden of factually supporting any prima facie conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fe. Cir. 1983). Distilling the invention down to the “gist” or “thrust” of an invention disregards the requirement of analyzing the subject matter “as a whole.” *See W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). If, viewing the invention as a whole, the Examiner does not produce a prima facie case, the Applicant is under no obligation to submit evidence of non-obviousness. *See In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). Inventors of unobvious compositions, such as those of the present invention, enjoy a *presumption* of non-obviousness, which must then be overcome by the Examiner establishing a case of prima facie obviousness by the appropriate standard. If the Examiner does not prove a prima facie case of unpatentability, then without more, the Applicants are entitled to grant of the patent. *See In re Oetiker*, 977 F.2d 1443.

As aforementioned, the Examiner has not satisfied the burden of establishing a prima facie case of obviousness. To establish a prima facie case of obviousness under 35 U.S.C. §103, the Examiner must meet three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest *all* the claim limitations. *See*, for example, *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicants respectfully assert that the Examiner fails to establish any of these criteria, and thus, fails to establish a prima facie case of obviousness.

First, Applicants respectfully assert that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the individual references or combine reference teachings. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *See In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). Applicants respectfully assert that there is no motivation to modify or combine McAnalley and Chen in the first instance. As aforementioned, McAnalley focuses on compositions in the form of tablets and capsules. Chen, on the other hand, focuses on powders and the use of those powders in different food and beverage applications. The present formulation was purposefully developed to not only provide a good source of fiber and vitamins, but also to provide a pleasant-

tasting drinkable beverage that would appeal to consumers. In order to accomplish this, the present composition was formulated to overcome the difficulties often associated with such beverages, namely sedimentation and the formation of off-flavors. The cited art fails to address either of these obstacles or ways by which to overcome them. Thus, Applicants respectfully assert that there is no suggestion or motivation to modify the references or combine reference teachings to make the present invention obvious in view thereof.

Additionally, as discussed previously, and in contrast to the Examiner's argument, a 'liquid' is not necessarily the same as a 'beverage,' therefore, Applicant assert that it would not be obvious to modify the 'liquid' of McAnalley in accordance with the disclosure of Chen to obtain a liquid having at least 50% water. Moreover, McAnalley merely mentions the use of a liquid as one of a laundry list of possible composition forms, which includes everything from powders, to gels, films and suppositories. Thus, Applicants respectfully assert that one skilled in the art would not be motivated to modify and/or combine the two references such that the present ready-to-drink beverage composition would be obvious in view thereof. Therefore, for these reason, Applicants respectfully assert that the first requirement for establishing a *prima facie* case of obviousness has not been satisfied.

Second, Applicants respectfully assert that there is no likelihood of success. Neither McAnalley nor Chen addresses or even recognizes the unique problems typically associated with formulating ready-to-drink beverage compositions as taught in the present invention, namely solubility and stability. Rather than solving these problems, both McAnalley and Chen avoid them altogether by using tablets, capsules and powders. Applicants respectfully assert that simply putting a supplement, in capsule or tablet form, into a liquid does not make a beverage as defined presently, as the compositions of McAnalley are not designed to be used in this manner to make a beverage composition. Similarly, putting the powder of Chen into water does not make the ready-to-drink beverage of the present invention, as the Chen beverages are to be consumed immediately prior to consumption. Additionally, Applicants respectfully re-assert that the Examiner's argument that the matrix of Chen may be added directly to water to form a beverage is incorrect. As aforementioned, Chen states that "the beverages of this invention are preferably obtained by adding to a beverage a powder composition of this invention." See Chen page 6, lines 2-3. Thus, contrary to the Examiner's statement, the composition of Chen must first be made into a powder before reconstitution with a beverage. In contrast, the present invention need not be dried to form a powder before mixing with a beverage. For this reason, Applicants respectfully assert that the cited references provide no likelihood of success for formulating the present stable beverage compositions.

Moreover, Applicants disagree with the Examiner's assertion that since Chen teaches 5% of a 'gum' as acceptable for use in an aqueous solution, it would be obvious to use 5% of a gum in the liquid of McAnalley. While Chen arguably teaches 5% of a gum as an acceptable amount for use in a solution, Applicants respectfully assert that even if it is assumed, for the sake of argument, that it would be obvious to use 5% of a gum in the liquid of McAnalley in the first instance, the present composition would still not be obvious in view thereof since neither Chen nor McAnalley provide a likelihood of success of the present ready-to-drink beverage compositions comprising at least about 50% water. As explained herein, the 'liquid' of McAnalley and the powders of Chen are not the same as the present beverage compositions. Thus, because neither reference teaches or suggests the incorporation of gums into ready-to-drink beverages, Applicants respectfully assert that the cited references provide no likelihood of success.

Furthermore, Applicants respectfully assert that McAnalley in view of Chen fails to teach or suggest *all* the claim limitations. As aforementioned, the references fail to teach the particular ready-to-drink beverage compositions claimed herein. More specifically, for the reasons stated previously, the references fail to teach ready-to-drink beverage compositions having at least about 50% water, which the present claims teach, as amended herein. Therefore, because McAnalley in view of Chen fails to teach all the limitations of the present claims, Applicants respectfully assert that the third criterion for establishing a *prima facie* case of obviousness has not been satisfied.

Thus, because McAnalley and Chen fail to provide the motivation to modify or combine the references, fail to provide a likelihood of success, and fail to provide a teaching of all limitations of the present claims, Applicants respectfully assert that a *prima facie* case of obviousness had not been established. Therefore, it is respectfully requested that the obviousness rejection under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the Examiner's rejections under 35 U.S.C. §§ 102 and 103 are improper. Reversal of such rejections is therefore respectfully requested.

Respectfully submitted,

By 
Bryn T. Lorentz
Attorney for Applicants
Registration No. 55,668
Telephone: (513) 634-2084

August 30, 2004